

REMARKS

Reconsideration of this application is respectfully requested. Claims 33-42 as amended are presented for consideration.

Status of the Claims

Claims 33-42 as amended remain in the case. Claims 34, 35 and 38 have been amended in accordance with the examiner's recommendations.

Applicant submits that the claimed subject matter is properly limited and focused on the detection of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma, and that primary claim 33 defines that the biological sample under test in the claimed method is selected from breast, pancreatic, lung, bladder, kidney or bone tissue. The examiner suggests that the claim, by the presence of 'comprises' as a modifier of the step, permits the broad interpretation taken with both Mack et al. and Gish, newly of record. However, neither of these references has as its objective and corresponding teaching disclosure, the detection of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma, which is an expressed aim and focus of the present method. In this context, the claim preamble is an integral part of the invention, and any third party disclosure not having this objective as its purpose and teaching, cannot function as an anticipation of the claimed invention.

Further discussion of the teachings of the references and their shortcomings in the rejection of the present claims, will be presented below in the individual discussions of the rejections under both Mack and Gish (US2007/0014801 A1).

Claim Rejections – 35 USC §112

Claims 34 35 and 38 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite in the presence of particular language in each. The noted claims have been amended as suggested by the examiner, and are believed to be free from the rejection. Accordingly, withdrawal of the rejections as based on 35 USC §112 is believed to be in order, and is requested.

Claim Rejection – 35 USC §102

Claims 33-42 are again rejected under 35 USC §102(e) as anticipated by Mack *et al.* (US 7,189,507). As this rejection may pertain to the claims particularly as presently amended, it is traversed.

Mack *et al.* disclose methods for diagnosing ovarian cancer comprising determining the expression of a gene as set forth in Tables 1-20 of the reference, wherein PTK7 is listed as one of hundreds of other gene sequences. Contrary to the examiner's assertion, Mack *et al.* do not disclose or suggest a method of screening and/or diagnosis of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject, as specifically defined and called for by the claims. The presently claimed method of screening is directed to biological samples taken from the compartments where the carcinomas in object are suspected, and thus delimits and distinguishes from the teachings of Mack *et al.*

Specifically, the examiner refers to a passage in Mack *et al.* at column 20, which teaches that ovarian cancer-associated sequences can be identified by comparing the expression in ovarian cancer relative to normal and/or non-malignant tissues. The passage at lines 52-57 states that in one embodiment the gene showing changes in expression as between normal and disease states are compared to genes expressed in other normal tissues, preferably normal ovarian but also including lung, heart, brain, liver, kidney, muscle, colon, small intestine, large intestine, spleen, bone and/or placenta. The purpose of this comparison is to check for expression of the gene in normal tissues in the body, and not to carry out a method of screening and/or diagnosis of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject.

Mack *et al.* further states that, if genes identified during the ovarian cancer screen are overexpressed in any significant amount in other tissues they are removed from the profile in order to minimize side effects (column 20, lines 58-65). Applicant submits that the passage referred to by the Examiner at lines 52-57 has to be read in the full context of the section in columns 19-20 which relates to the identification of ovarian cancer-associated sequences i.e. to identify for the first time genes which are associated with ovarian cancer. This passage does not mention nor relate in any way to a method of screening or diagnosis of cancers and certainly does not teach the skilled person that carcinoma selected from breast, pancreatic, lung, bladder or kidney cancer or

osteosarcoma may be diagnosed by detecting or quantifying PTK7 in these specific tissues, as required by claim 33 of the present invention. Applicant accordingly reiterates that primary claim 33 and the claims depending from it, are novel and not anticipated by the disclosure of Mack *et al.*

Accordingly, the rejection based on Mack *et al.* as it is applied to the present claims, is believed to be overcome, and reconsideration and withdrawal thereof is requested.

Claims 33-42 have also been rejected under 35 USC §102(e) as anticipated by Gish *et al.* (US PGPub 2007/0014801 A1). As this rejection may pertain to the claims particularly as presently amended, it is traversed.

Gish *et al.* is, in certain respects, similar in its focus and disclosure, and corresponding distinction from the presently claimed invention, to Mack *et al.* discussed above. The relevance and anticipatory effect of Gish *et al.* is not established or enhanced because of the perceived identity of the referenced protein sequence to that of SEQ. ID NO:1 of the present application. The invention under examination is not the protein but a specific method of screening for an equally specific repertoire of carcinomas, which it is submitted, is not anticipated by Gish *et al.*

Specifically, Gish *et al.* is exclusively concerned with prostate cancer. The Examiner refers to page 11 of Gish *et al.*, which describes the identification of prostate cancer-associated sequences. As stated above, this is a similar disclosure to that described above with respect to Mack *et al.* This passage of Gish *et al.* is concerned with the identification of sequences that are differentially expressed in prostate cancer versus non-prostate cancer tissue. Paragraph [0112] on page 11 of Gish *et al.*, states that other suitable tissue comparisons include comparing prostate cancer samples with metastatic cancer samples from other cancers such as lung, breast, gastrointestinal cancer, ovarian, etc. This disclosure on page 11 is not concerned with a method of screening or diagnosis of cancers and certainly does not teach the skilled person that carcinoma selected from breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma, may be diagnosed by detecting or quantifying PTK7 in these specific tissues, as required by claim 33 of the present invention.

The Examiner also refers to page 22 and page 23 of Gish *et al.*, which is concerned with detection of prostate cancer for diagnostic and therapeutic applications. However, the only teaching in this passage of tissues to be screened relates to evaluating expression levels of genes in normal prostate tissue and prostate cancer tissues. Gish *et al.* does not mention any other tissues for diagnostic or screening purposes.

Therefore, for similar reasons discussed above for Mack *et al.*, present claim 33 and the claims dependent therefrom, are also novel over the disclosure of Gish *et al.* Accordingly, reconsideration and withdrawal of the rejection as it may be based on Gish *et al.* is likewise, believed to be in order, and is requested.

Conclusion

To summarize, therefore, the features of the present method are believed to be clearly recited in the claims as amended and presented for consideration, and are likewise believed to clearly distinguish the references applied in rejection. Applicant submits that patentable subject matter is clearly defined and that all grounds of rejection have been overcome. Should the Examiner believe that other issues remain for resolution, she is invited to call the undersigned at the number listed below.

In view of the above and foregoing, reconsideration and withdrawal of the outstanding grounds of objection and rejection and early allowance of the claims as amended is believed to be in order and is courteously solicited.

Respectfully submitted,

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Dated: June 7, 2010

ENCLOSURE: Request for Two (2) Month Extension of Time